

Remarks/Arguments

Claims 14-19, 21, 22 and 24-33 are pending and subject to examination. Reconsideration and allowance of these claims is respectfully requested in view of the above changes and the following remarks.

Specification

The specification has been reviewed and the appropriate corrections have been made. Tween is a registered trademark of ICI Americas. The generic name is polysorbate 20.

Response to Section 112 1st Paragraph Rejection

Claims 14-33 stand rejected under 35 USC 112, 1st paragraph. The rejection admits that the specification is enabling for a method of water disinfection with a composition comprising (a) an effective amount of an emulsifier selected from the group provided in claim 22, (b) an effective amount of an essential oil (presumably selected from clove oil, eucalyptus oil and Kapur Tulsi oil), and (c) an effective amount of an optional electrolyte, and optional carrier oil selected from the group provided in claim 30, where the contaminating microorganisms are *E. coli*, *Salmonella typhi* and *Vibrio cholerae*. The rejection alleges that the specification is not enabling for a composition comprising (a) any and all emulsifiers, (b) any and all essential oils, and (c) any and all optional electrolytes and any and all optional carrier oils.

Without acquiescing in the rejection, and in an effort to expedite prosecution, claim 14 has been amended to recite the essential oils from claim 20. The optional carrier oil has been indicated as comprising a plant oil (as stated in the specification at page 10, line 24).

Emulsifiers

The rejection alleges that the specification does not provide guidance as to how to identify "any and all emulsifiers" which can be used in the making of a composition for treating water contaminated with pathogenic microorganisms.

Applicant enjoys a presumption that the specification, which discloses how to make and use a claimed invention, complies with the first paragraph of 35 U.S.C.112 unless there is a reason to doubt the objective truth of the specification. In re Marzocchi, 439 F.2d 220, 169

USPQ 367 (CCPA 1971). In establishing a *prima facie* basis to deny patentability under the first paragraph of 35 U.S.C. 112 for lack of adequate enabling support, it is incumbent upon the examiner to explain why he doubts the truth or accuracy of the supporting specification and to buttress assertions with evidence or cogent reasoning inconsistent with the specification. In re Strahilevitz, 668 F.2d 1229, 212 USPQ 561 (CCPA 1975); In re Bowen, 492 F.2d 859, 181 USPQ 48 (CCPA 1947); In re Marzocchi, 439 F.2d 220, 169 USPQ 367 (CCPA 1971). Any assertion that the enabling disclosure is not commensurate in scope with the protection sought must be supported by evidence or reasoning substantiating the doubts so expressed. In re Dinh-Nguyen, 181 USPQ 46, 47 (CCPA 1974).

The number and variety of examples is irrelevant if the disclosure is "enabling" and sets forth the "best mode contemplated". In re Borkowski, 164 USPQ 642 (CCPA 1970). An applicant need not provide a specific example of everything embraced by a broad claim. In re Anderson, 176 USPQ 331 (CCPA 1973).

The specification states at page 10, line 8+, that any suitable emulsifier may be used to emulsify the essential oil for use in the method of the present invention. Numerous emulsifiers are listed. The specification states that the emulsifier may be present in any concentration sufficient to allow formation of a stable oil-in-water emulsion of the essential oil and optional carrier. The rejection alleges that the state of the art at the time the invention was made suggests that not all emulsifiers in combination with an essential oil would have bactericidal activity. In support of this position, the rejection points to Beylier, which allegedly teaches that when testing the antimicrobial activity of essential oils, one should not use cationic emulsifiers because they present a slight bactericidal activity. Thus, the rejection reasons that Beylier advises the use of nonionic emulsifiers that have no antibacterial activity for the emulsification of essential oils, for use in applications needing an antibacterial agent.

The teachings of Beylier do not buttress Examiner's assertions that the specification is non-enabling with respect to the emulsifier claim element. Beylier describes a study to whereby essential oils were screened for bacteriostatic activity. Beylier instructs against the use of cationic emulsifiers not because they are ineffective in emulsifying essential oils, but merely because their slight intrinsic biocidal activity would confound the test results in evaluating the intrinsic biocidal activity of the essential oil. The constraints place by Beylier on the selection of

an emulsifier for formulating essential oils for *activity screening* is irrelevant to the selection of an emulsifier for formulating a working essential oil-based composition for disinfecting water. Whether or not intrinsic biocidal activity of the emulsifier would mask the true activity level of the essential oil component is inconsequential, and would not lead one skilled in the art to dismiss cationic compounds as emulsifiers for essential oils. Indeed, the additional disinfecting activity of a bactericidal emulsifier would be beneficial (although not necessary) in formulating a bactericidal composition. Hence, the teachings of Beylier do not provide the supporting evidence or reasoning to rebut the truth or accuracy of the specification with respect to the scope of useful emulsifiers.

Electrolytes and Carrier Oils

The rejection alleges while applicant has demonstrated the use of effective amounts of Na_2HPO_4 and NaCl as the optional electrolyte, and effective amounts of groundnut oil and saffola oil as the optional carrier oil, the specification does not enable the used of “any and all” carrier oils and “any and all” electrolytes in the practice of the invention.

Carrier oils and electrolytes are preferred but *optional* components of the composition used in the practice of the present invention. As an *optional* component, it is not seen how the failure to limit the claimed range of carrier oil to the specific oils groundnut and saffola oil, in specific amount ranges, represents a failure of enablement under 35 USC 112. A wide selection of such optional carrier oils is provide in the specification (page 10, line 21 - page 11, line 8). The specification states that carrier oils allow the formation of finer and more stable emulsions than may be achievable with an essential oil alone. But clearly the carrier oil is not essential. Similarly, it is not seen how the failure to limit the claimed range of another optional component - the electrolyte - to the specifically exemplified material and concentration ranges, represents a failure of enablement to component. The specification describes NaCl and Na_2HPO_4 as preferred electrolytes (page 11, lines17-22).

The specification states that useful concentrations of carrier oil and electrolyte may be determined by the General Methodologies set forth at page 13+. Preferred ranges of amounts for the optional carrier oil and electrolyte are provided in the specification at pages 11-12. If an applicant need not provide a specific example of everything embraced by a broad claim, In re Anderson, 176 USPQ 331 (CCPA 1973), this must be particularly true of optional ingredients.

Indeed, the role of the carrier oil and electrolyte as *optional* ingredients is inconsistent with Examiner's requirement that their selection be limited in the claims to the specific materials and amounts utilized in working examples.

The rejection points out to an "admission" in the specification at page 21, lines 12-15, that "negative" disinfection results were obtained for emulsions E11-E15, containing differing concentrations of the carrier oil groundnut, when used in 1 liter volume. The rejection also points to the statement at page 24, lines 9-10, that 0.1 and 0.05 ppm electrolyte performed better than "electrolyte at lower concentrations".

There is no requirement that each compound within a claim be equally useful for each contemplated application. Ex parte Cole, 223 USPQ 94, 95 (Bd.App.1983). "Disclosure in the specification sufficient to enable practice of the invention by one skilled in the art, taking into account obvious modifications of the reaction ratios of specific examples, is all that is required. It is not the function of the claims to specifically exclude either possible inoperative substances or ineffective reactant proportions." In re Dinh-Nguyen, 181 USPQ 46, 48 (CCPA 1974). The mere fact that under some conditions, some amounts or combinations of ingredients may prove less effective, does not render the specification lacking in enabling disclosure. As to the amount of electrolyte, the fact that some concentrations *are more effective than others* is not a reason for concluding that the specification is non-enabling. It would be a rare occurrence indeed for the activity of a bio-affecting composition to be constant over all possible concentrations of ingredients. The general and specific disclosures of the specification give sufficient guidance to one of ordinary skill in the art to make compositions for use in the claimed method, which compositions may optionally contain a carrier oil and an electrolyte.

Without admitting the correctness of the rejection, and in an effort to advance prosecution, claim 14 has been amended to indicate that the optional carrier oil is a plant oil. This is supported by the specification at page 40, line 24.

Pathogenic organisms

The rejection alleges that the specification does not enabling for treating water contaminated with any and all pathogenic microorganisms.

The specification teaches that the claimed invention is effective for disinfecting potable liquids contaminated with a wide range of microorganisms, including *E. coli*; *Salmonella*, especially *Salmonella typhi*; *Vibrio*, especially *Vibrio cholerae*; *Shigella*; *S. Aureaus*; *Bacillus subtilis*; *P. aeuroginosa*; *S. flexneri*; and *P. vulgaris*. Claim 14, as amended, is directed to a water disinfection method which utilizes as the active agent at least one of clove, eucalyptus and Kapur Tulsi oil.

The specification *exemplifies* that clove, eucalyptus and Kapur Tulsi oil are active against three diverse microorganisms, *E. coli*, *Salmonella typhi*, and *Vibrio cholerae*. See Tables 1 and 2, pages 116-17. The rejection fails to set forth any evidence or reasoning to doubt the teachings of the specification in regard to the usefulness of these three oils in treating water contaminated with a broad range of microorganisms. Indeed, the activity of the essential oils against three bacteria genii as diverse as *Escherichia*, *Salmonella* and *Vibrio* indicates otherwise. In the absence of such evidence or reasoning, the rejection as it relates to the scope of organisms should be withdrawn.

Response to Section 112 2nd Paragraph Rejections

Claim 16

Claim 16 has been amended as suggested by Examiner.

Claim 20

Claim 20 has been cancelled and the subject matter combined with claim 14. Thus, the rejection will be treated as if made against claim 14.

Claim 14 is not indefinite with respect to the expression "Kapur Tulsi oil". "Kapur" is the Indian word for camphor. See the attached page from *The American Heritage® Dictionary of the English Language*, 4th ed., 2000. Tulsi is an Indian word for the plant *Ocimum sanctum*. See, for example, the attached abstract of Ehma et al., *Indian Journal of Clinical Biochemistry*. 2001 Jul; 16(2): 190-4. Kapur Tulsi oil is an oil containing camphor and the essential oil of *Ocimum sanctum* in equal proportions.

Claims 22-25

Claim 22 has been amended to delete the trademarks Tween, Myrj and Bryj. Claim 23 has been canceled. Claim 24 has been amended to replace the trademark "Tween" with the generic term "polysorbate".

Claims 25, 26, 28 and 29

Claims 25, 26, 28 and 29 have been amended to indicate that the percentages expressed are weight percentages. This is consistent with the usage in the specification at page 10, lines 16-20.

Response to Section 102 Rejection

Claims 14, 16, 20, 21 and 25 have been rejected as allegedly anticipated by Bose *et al.* Claim 20 has been cancelled and the subject matter combined with claim 14.

Bose *et al.* discloses the results of a test in which several Indian essential oils were emulsified and tested for their bactericidal efficiency by the so-called Rideal-Walker test, and by the so-called Chick-Martin test, as modified by Garrod (presence of 5% yeast suspension). The Rideal-Walker test has been employed in various scenarios to evaluate the disinfectant efficiency of materials. The test compares the germicidal effect of a substance to the germicidal effect of phenol. The Chick-Martin test was designed to test the efficiency of a germicidal preparation in the presence of interfering organic material, such as feces, coal-tar, milk and yeast suspensions.

The germicidal activity of various essential oils were tested by Bose *et al.* In each test, 1% essential oil was emulsified with 1% potassium oleate as an emulsifying agent, and 0.5% potassium carbonate as an emulsion stabilizer. Bose *et al.* refer to the potassium oleate as "soap". The "soap" was prepared by refluxing a mixture of alcoholic solution of oleic acid and alcoholic potash. The essential oil, soap and carbonate on mechanical mixing yielded a creamy paste which was diluted with. Experiments were designed to test the germicidal efficacy of these preparations in the presence of yeast suspension. Lemon-grass oil, having been found to be the most active essential oil, was subjected to further tests in the presence of feces, serum and milk.

Claim 14 defines a method of disinfecting water contaminated with pathogenic microorganisms, comprising treating the contaminated water for a period ranging up to 24 hours with a composition *enabling the water to be potable*. The emulsions prepared by Bose *et al.* for testing the germicidal effect of certain essential oils could not result in potable water since they

are based on soap, which is clearly not potable. There is no teaching of any other emulsifier by Bose *et al.* Clearly, Bose *et al.* do not teach, or even contemplate, a composition that would enable disinfection of water to potability. Some of the experimental conditions in the Bose *et al.* study included organic loadings such as 3% feces or 5% yeast suspension. These organic loading levels might be found in wastewater or sewage, but never in drinking water. The 1949 teachings of the Bose *et al.* reference are directed to hygiene of waste streams, not the disinfection of potable water sources. This is consistent with the experimenters' selection of soap as an emulsifier which would be inappropriate for treating drinking water. Bose *et al.* do not suggest a method for disinfecting water that would be considered for internal consumption.

Bose *et al.* does not anticipate that invention of claim 14, because it does not disclose a method of disinfecting water with a composition enabling to water to be potable following treatment. Reconsideration and withdrawal of the Section 102 rejection of claims 14, 16, 21 and 25 is respectfully requested.

Response to Section 103 Rejections

Claims 14-19, 25, 26, 32 and 33 are rejected as allegedly obvious over Nitas in view of Rideal. Claims 14 and 22-24 are rejected as allegedly obvious over Emerson *et al.* in view of Lawless and Belliert *et al.* Claims 14-19, 25-29, 32 and 33 are rejected as allegedly obvious over Nitsas and Rideal in view of Benn *et al.* Claims 14 and 30-31 are rejected as allegedly obvious over Nitas and Rideal in view of Kurita *et al.*, Jovanic, Hamernik, Eibl *et al.* and Baldelli. Claims 14, 22-24 and 30-31 are rejected as allegedly obvious over Emerson *et al.*, Lawless and Belier *et al.* in view of Kurita *et al.*, Jovanic, Hamernik, Eibl *et al.* and Baldelli.

Claim 20, which is not subject to any of the aforesaid obviousness rejections, has been combined with claim 14. Claim 14, and all its dependent claims, are thus free of all obviousness rejections.

Conclusion

The claims remaining in the application are believed in condition for allowance. An early action to that end is earnestly solicited.

Respectfully submitted,

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